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PRD2007-11

## Proposed Registration Decision

# 1-methylcyclopropene

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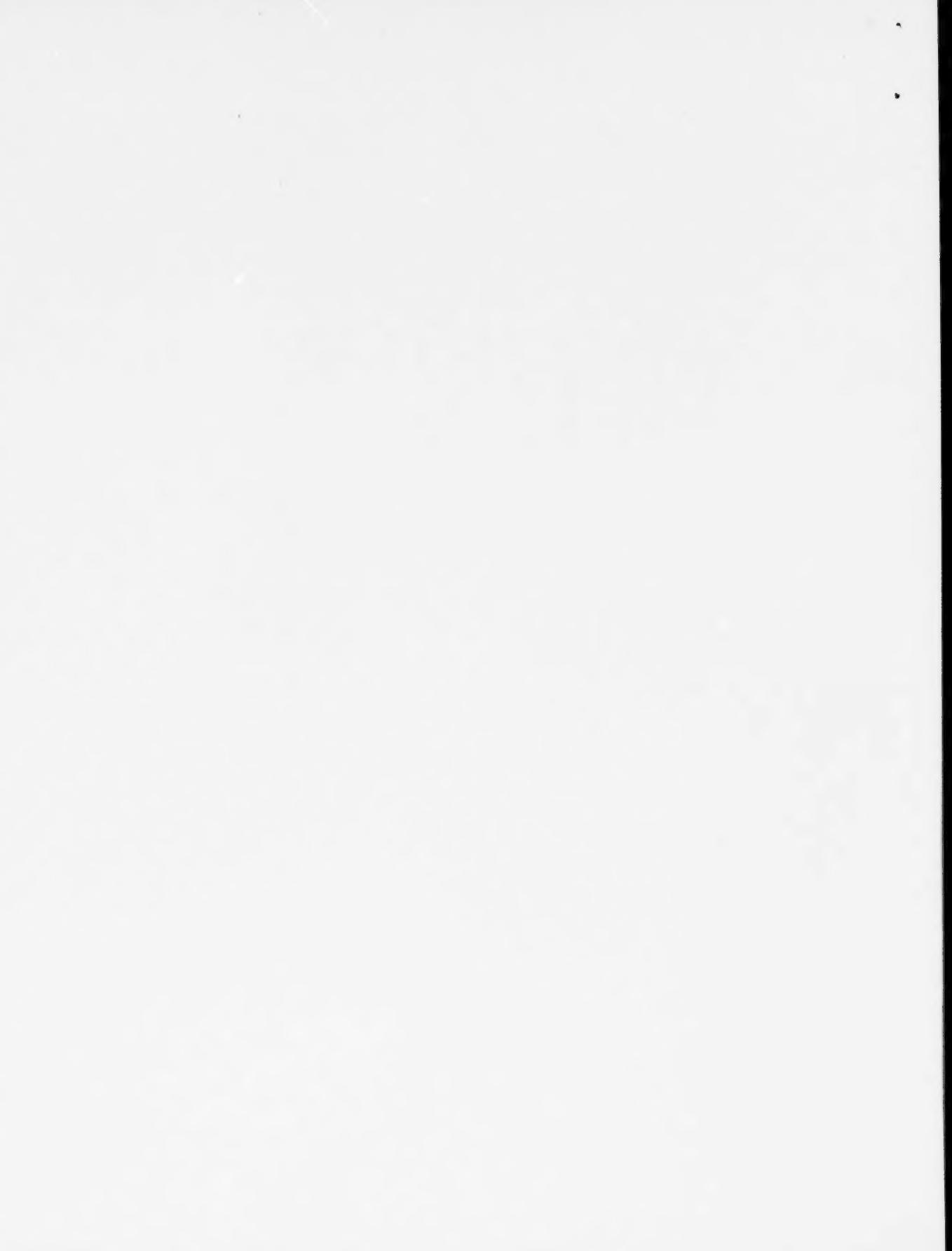
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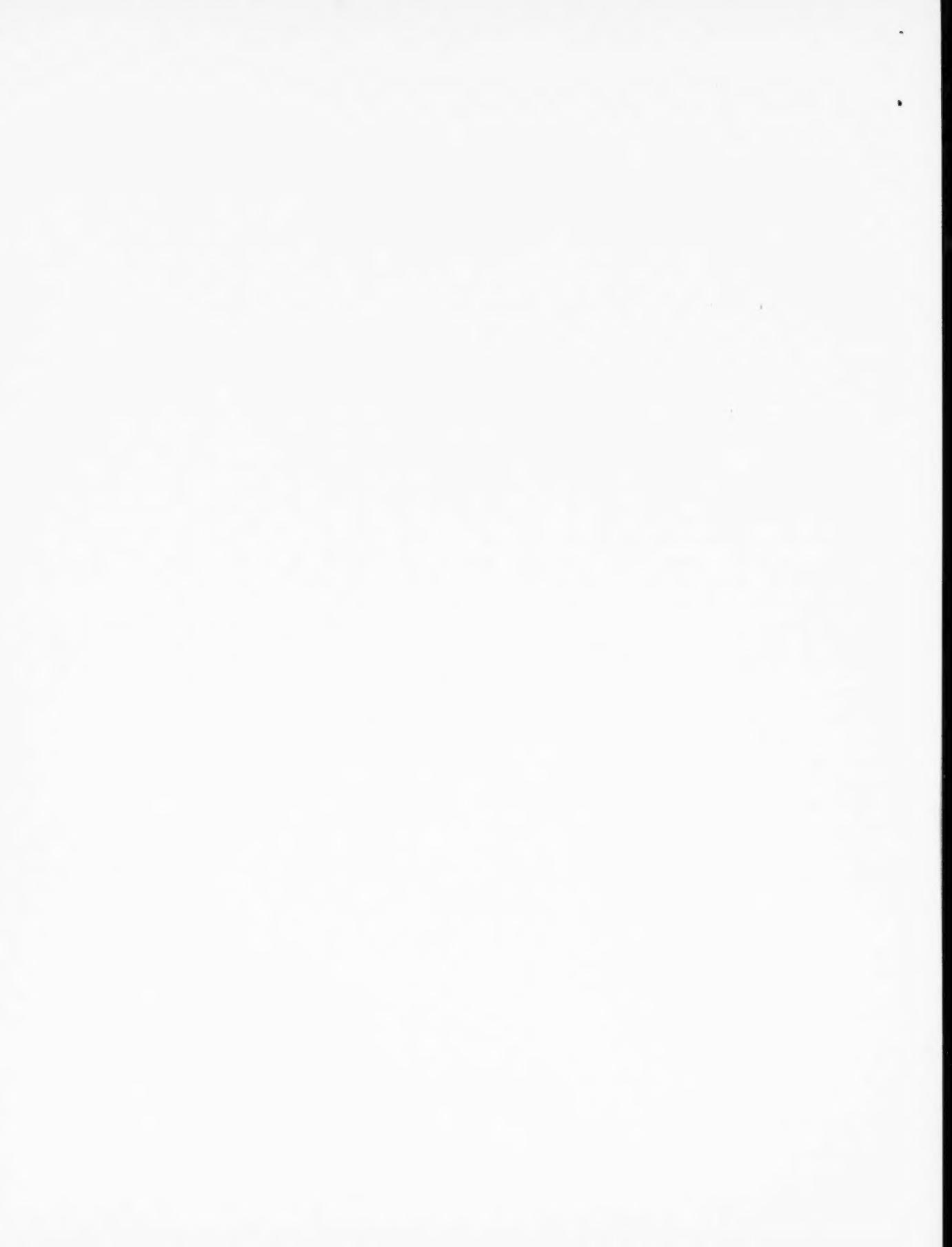
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# Overview

## Proposed Registration Decision for 1-methylcyclopropene

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing full registration for the sale and use of technical grade active ingredient 1-methylcyclopropene (1-MCP) Technical and the end-use product SmartFresh Technology to slow senescence and maintain firmness of apple fruit following harvest.

An evaluation of available scientific information found that, under the approved conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

This Proposed Registration Decision is a consultation document<sup>1</sup> that summarizes the science evaluation for 1-methylcyclopropene and the reasons for the decision. It also describes risk-reduction measures that will be required to further protect human health.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessment of 1-methylcyclopropene.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

## What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration<sup>2</sup>. The Act also requires that products have value<sup>3</sup> when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act* (<http://laws.justice.gc.ca/en/P-9.01/92455.html>)

<sup>2</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act* (<http://laws.justice.gc.ca/en/P-9.01/92455.html>)

<sup>3</sup> "Value" as defined by Subsection 2(1) of the *Pest Control Products Act* (<http://laws.justice.gc.ca/en/P-9.01/92455.html>): "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at [www.pmra-ara.gc.ca](http://www.pmra-ara.gc.ca).

Before making a registration decision on 1-methylcyclopropene, the PMRA will consider all comments received from the public in response to this consultation document<sup>4</sup>. The PMRA will then publish a Registration Decision document<sup>5</sup> on 1-methylcyclopropene, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

## What is 1-methylcyclopropene?

1-methylcyclopropene is a plant growth regulator that inhibits ethylene. It is applied to apples in airtight rooms shortly after harvest to prolong storage life. The inhibition of ethylene action and synthesis delays the onset of the climacteric period of fruit ripening in which ethylene production and respiration increase rapidly. The maturation of the fruit is, therefore, delayed with the result that fruit remains firmer for a longer period.

## Health Considerations

### Can Approved Uses of 1-methylcyclopropene Affect Human Health?

**1-methylcyclopropene is unlikely to affect your health when used according to the proposed label directions.**

Potential exposure to 1-methylcyclopropene may occur through diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

<sup>4</sup> "Consultation statement" as required by subsection 28(2) of the Pest Control Products Act (<http://laws.justice.gc.ca/en/P-9.01/92455.html>)

<sup>5</sup> "Decision statement" as required by subsection 28(5) of the Pest Control Products Act (<http://laws.justice.gc.ca/en/P-9.01/92455.html>)

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using 1-methylcyclopropene products according to label directions.

The technical grade active ingredient 1-methylcyclopropene and the end-use product SmartFresh Technology did not exhibit any adverse affects in the acute studies. Consequently, no label statements are required. 1-methylcyclopropene was not genotoxic and there was also no indication that 1-methylcyclopropene caused damage to the nervous system. The technical grade active ingredient is a gas and no long-term exposure is expected. Subsequently, no long-term studies were conducted. The first signs of toxicity in animals given daily doses of 1-methylcyclopropene over longer periods of time were effects on the spleen, liver and kidneys. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When 1-methylcyclopropene was given to pregnant animals, no effects were observed on the developing fetus, young animals or the mothers. This indicates that the fetus or young animals were not more sensitive than the mothers and specific protection is not required in the risk assessment.

## **Residues in Water and Food**

### **Dietary risks from food and water are not of concern.**

1-methylcyclopropene is a volatile gas and all matrices measured (including stored apples) had no measurable residues. The proposed use of SmartFresh Technology (containing 3.3% w/w 1-MCP) as a post-harvest treatment, intended to delay the ripening of mature stored apples, does not pose an unacceptable dietary risk to any segment of the population, including infants, children, adults and seniors. There is negligible concern regarding the 3-chloro-2-methylpropene (CMP) impurity, as the level in the end-use product is very low (0.000561%).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted in sealed treatment chambers using SmartFresh Technology containing 1-methylcyclopropene on apples were sufficient to propose an MRL. This MRL can be found in the Science Evaluation section, Appendix I, of this consultation document.

## **Occupational Risks From Handling SmartFresh Technology**

**Occupational risks are not of concern when SmartFresh Technology is used according to label directions, which include protective measures.**

During early re-entry to treatment areas, individuals can come in direct contact with 1-methylcyclopropene through inhalation of vapours or by skin contact with vapours. For this reason, the label specifies that anyone re-entering treatment areas early must wear long-sleeved shirts, long pants and chemical-resistant gloves, as well as respiratory protection. In taking into consideration these requirements and the expected brief occupational exposure, risk to commercial applicators or workers is not a concern.

For bystanders, exposure is expected to be much less than that of commercial applicators and is considered negligible. Therefore, risks to bystanders are not of concern.

## **Environmental Considerations**

### **What happens when 1-methylcyclopropene is introduced into the environment?**

1-methylcyclopropene is used indoors, and is not persistent in the terrestrial and aquatic environment once vented to the atmosphere. Thus, the risk to terrestrial and aquatic organisms is expected to be negligible.

1-methylcyclopropene is a gas and is to be used indoors as a postharvest treatment on apples, therefore there will be no exposure to the environment during use. However, exposure will occur once treatment rooms are vented after use. The maximum concentration of 1-methylcyclopropene in air would be 1 ppm after venting based on the maximum application rate, applied once per year in a closed apple storage facility in late summer (August to October). Once vented, the primary route of transformation of 1-methylcyclopropene gas will be via reactions with ozone, hydroxyl radicals and photolysis. Based on its short half-life (up to 4.4 hours), its vapour state, and time of venting release (August to October when birds are no longer nesting and foraging activity of beneficial insects has decreased), 1-methylcyclopropene is expected to pose negligible risk to aquatic and terrestrial organisms.

## **Value Considerations**

### **What is the Value of SmartFresh Technology?**

**1-methylcyclopropene, a plant growth regulator, slows firmness loss and extends marketing life of apples.**

A single post-harvest application of SmartFresh Technology to apples slows loss of firmness by delaying fruit ripening and senescence, and also reduces the incidence of superficial scald, a physiological skin disorder, following removal from storage. As a result, use of SmartFresh Technology maintains fruit quality and extends the marketability period of apple fruit destined for either domestic or export market channels.

1-methylcyclopropene is the first plant growth regulator registered for postharvest use on apples. The only alternative product registered to delay apple maturity and maintain fruit quality is ReTain Plant Growth Regulator (Registration Number 25609), with the active ingredient aminoethoxyvinylglycine hydrochloride (15% guarantee). ReTain Plant Growth Regulator is mainly marketed for use on apple trees to control preharvest fruit drop, with the secondary claims that it "may also delay fruit maturity, help maintain fruit quality (e.g. firmness) and may reduce the incidence and/or severity of watercore". ReTain Plant Growth Regulator is applied four weeks before the anticipated harvest date and, therefore, has a different use pattern than SmartFresh Technology.

## **Measures to Minimize Risk**

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of SmartFresh Technology to address the potential risks identified in this assessment are as follows:

### **Key Risk-Reduction Measures**

#### **Human Health**

As there is a concern with workers coming into direct contact with 1-methylcyclopropene through inhalation of vapours or by skin contact with vapours, anyone re-entering treatment areas prior to the completion of ventilation must wear long-sleeved shirts, long pants and chemical-resistant gloves, as well as respiratory protection.

## **Next Steps**

Before making a registration decision on 1-methylcyclopropene, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Registration Decision document, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and the Agency's response to these comments.

## **Other Information**

At the time the PMRA makes its registration decision, it will publish an Evaluation Report on 1-methylcyclopropene (based on the Science Evaluation section of this consultation document). In addition, the test data on which the decision is based will also be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

## **Science Evaluation**

### **1.0 The Technical Grade Active Ingredient, its Properties and Uses**

#### **1.1 Identity of the Technical Grade Active Ingredient**

Refer to the Regulatory Note REG2004-07, 1-methylcyclopropene for a detailed assessment of the chemistry database for 1-methylcyclopropene and SmartFresh Technology.

#### **1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product**

See Section 1.1.

#### **1.3 Directions for Use**

SmartFresh Technology, containing 3.3% 1-methylcyclopropene (1-MCP), is a plant growth regulator that is applied to apples following harvest to slow firmness loss and extend marketing life. Application of SmartFresh Technology is made by means of a proprietary generator that is placed within the airflow of the internal refrigeration system of the enclosed room containing the apples to be treated. Following the addition of water and the single soluble packet to the device, the active ingredient is released as a vapour and is circulated throughout the room for a 24-hour period. There are 20 soluble packet sizes that range from 2.5 to 310.6 g product for treatment of room volumes that range from 40 to 5400 m<sup>3</sup>. The specific concentration of 1-MCP achieved is a function of the size of the soluble packet and the specific volume of the treatment room, resulting in delivered concentrations that range from approximately 0.67 to 1.0 ppm. SmartFresh Technology is applied in ambient temperature, refrigerated or controlled atmosphere food storage facilities. Following treatment that is made within 10 days of harvest, fruit not destined for immediate marketing are then stored in accordance with standard commercial practices.

#### **1.4 Mode of Action**

The active ingredient, 1-MCP, competes with ethylene at membrane-bound ethylene receptor proteins within the fruit, thereby inhibiting both the action of ethylene and the synthesis of additional ethylene via a positive feedback mechanism from the ethylene-receptor complex. The inhibition of ethylene action and synthesis delays the onset of the climacteric period of fruit ripening in which ethylene production and respiration increase rapidly. The maturation of the fruit is, therefore, delayed with the result that fruit retains its firmness for a longer period.

### **2.0 Methods of Analysis**

Refer to the Regulatory Note REG2004-07, *1-methylcyclopropene* for an assessment of analytical methods.

### **3.0 Impact on Human and Animal Health**

Refer to the Regulatory Note REG2004-07, *1-methylcyclopropene* for a detailed assessment of the toxicological, exposure and dietary risk database for 1-methylcyclopropene and SmartFresh Technology. Refer to Appendix I of this Proposed Registration Decision for supplemental maximum residue limit information.

### **4.0 Impact on the Environment**

Refer to the Regulatory Note REG2004-07, *1-methylcyclopropene* for a detailed assessment of the environmental database for 1-methylcyclopropene and SmartFresh Technology.

### **5.0 Value**

#### **5.1 Effectiveness Against Pests**

As a condition of registration (refer to Regulatory Note REG2004-07), additional data were required to confirm the need for the labelled maximum use concentration of 1.0 ppm 1-MCP. Data were also required to confirm efficacy when applied to fruit in large scale commercial storage facilities. Refer to the Regulatory Note REG2004-07, *1-methylcyclopropene* for a detailed assessment of the originally submitted value database for SmartFresh Technology.

Data were submitted from one small-scale study conducted in Ontario in the 2004–2005 storage season. The response of stored and unstored fruit of three cultivars, ‘McIntosh’, ‘Empire’ and ‘Red Delicious’ to SmartFresh Technology was assessed. Fruit was initially harvested at or near optimum maturity with subsequent harvests having taken place 5 and 10 days afterwards. Immediately following each harvest, fruit were cooled overnight to 0–1°C. To determine the effect of delaying application, separate fruit samples were held for 3, 7, or 10 days (to simulate application delay) at this temperature prior to treatment with SmartFresh Technology. SmartFresh Technology was then applied at 1-MCP concentrations of 0, 0.625 or 1.0 ppm for 24 hours at 0–1°C.

The effect of harvest date, application delay, and 1-MCP concentration on fruit firmness and internal ethylene concentration of apple fruit not subjected to storage (e.g. fruit intended for immediate marketing) was assessed. The effect of harvest date, treatment delay, 1-MCP concentration and post-storage period on fruit firmness, ethylene production, and respiration of apple fruit subjected to refrigerated air (RA) or controlled atmosphere (CA) storage was assessed.

SmartFresh Technology was effective in slowing the loss of firmness of either unstored fruit or fruit of 'McIntosh', 'Empire' and 'Delicious' apples that were stored in RA for up to six months or in CA conditions for up to 12 months. Firmness response of fruit treated with 1-MCP varied with storage regime, storage period, cultivar, and post-storage period. It was generally effective for fruit harvested during the ten-day period following optimum maturity and for fruit that were held after harvest for up to 10 days at low temperature prior to treatment. Additionally, a concentration of 1.0 ppm did sometimes result in more firmness retention than that observed in fruit treated with 0.625 ppm.

In a commercial-scale study, SmartFresh Technology, applied at a concentration of 1.0 ppm 1-MCP from one to three days after harvest in commercial storage rooms of up to 1182 m<sup>3</sup>, was effective in slowing the loss of firmness of 'Empire' and 'Delicious' apples that were either not subjected to storage or stored under RA for up to six months or under CA for up to 12 months. Since firmness is typically lost more rapidly in RA than CA, greatest response to 1-MCP was generally observed in RA. In RA, SmartFresh Technology slowed the loss of firmness over the 14 day post-storage period in which fruit were held at 22°C to simulate the conditions and timeframe under which fruit would be marketed. In CA, the efficacy of SmartFresh Technology in maintaining firmness was most apparent at the end of the 14 day post-storage period.

SmartFresh Technology can be supported for full registration from a value standpoint at a use concentration of up to 1.0 ppm 1-MCP. The data submitted indicates that an increased firmness response to the 1.0 ppm concentration over that of the lower (0.625 ppm) concentration would not be expected for fruit of all apple cultivars; however, since fruit of several cultivars are typically stored in the same storage room, a use concentration of up to 1.0 ppm 1-MCP can be supported, with the actual use concentration ranging from 0.67 to 1.0 ppm 1-MCP, depending on the "System" used (combination of soluble package weight and treatment room volume). While data were submitted in support of a fruit firmness claim for apples that were cooled within 24 hours after harvest and then treated with SmartFresh Technology for up to 10 days after harvest, a claim of superficial scald reduction is supported only for apples that are treated within 72 hours after harvest at optimum maturity, and stored for up to 180 days. As the claim of flesh firmness maintenance can now be fully supported, other claims that were accepted under the original application for registration can also be fully supported.

### **5.1.1 Acceptable Efficacy Claims**

The submitted efficacy data established the lowest effective concentration of SmartFresh Technology for post-harvest use on apples and support the use direction and efficacy claims that are summarized in Table 5.1.1.1.

**Table 5.1.1.1 Acceptable Claims for SmartFresh Technology**

Applicant-Proposed Claims	Supported claims
<b>Use directions</b>	
Lowest effective concentration (rate) of 1-MCP: maximum 1.0 ppm	Supported. The exact concentration of 1-MCP used is a function of room volume and "System" used, i.e. soluble packet size; actual concentration ranges from 0.67 to 1.0 ppm.
Application timing: within ten days after harvest	Supported for apples that are cooled to 0–3°C within one day after harvest, otherwise treatment to be made within one day after harvest at treatment temperatures of up to 23°C.
Application equipment: Use of a proprietary device to apply the proposed SmartFresh Technology formulation (3.3% 1-MCP)	Supported.
Application sites: ambient temperature, refrigerated or controlled atmosphere food storage facilities that can be made airtight during treatment	Supported.
Application duration: 24 hours	Supported.
Number of applications per year: one per any one lot of apples	Supported.
Application to apple fruit to be stored in refrigerated air or controlled atmosphere	Supported for the maximum practical storage period of 6 months in refrigerated air or 12 months in controlled atmosphere conditions.
<b>Efficacy claims</b>	
Maintaining fruit firmness	Supported.
Reduction in internal ethylene production	Supported.
Reduction in respiration	Supported.
Delay in ripening and senescence	Supported.
Preventing superficial scald on apple fruit	Supported for apples that are treated within 3 days following harvest at optimum maturity and stored for up to 6 months.

## 5.2 Phytotoxicity to Target Plant Products

No adverse effects were reported in or on apple fruit following treatment with 1-MCP, with the exception of external carbon dioxide (CO<sub>2</sub>) injury. Data from two trials indicated that 1-MCP may exacerbate CO<sub>2</sub> injury in controlled atmosphere storage, particularly for fruit that had received a pre-harvest treatment of ReTain. The following warning statement is therefore required on the label: "Treatment with SmartFresh Technology followed by controlled atmosphere storage may increase incidence and severity of CO<sub>2</sub> injury."

### **5.3 Impact on Succeeding or Adjacent Crops**

SmartFresh Technology is only intended for postharvest use on apple fruit in enclosed food storage facilities; therefore use of this product is not expected to impact other crops.

### **5.4 Economics**

No market analysis was provided for this application.

### **5.5 Sustainability**

#### **5.5.1 Survey of Alternatives**

The only alternative product registered to delay apple maturity and maintain fruit quality is ReTain Plant Growth Regulator (Registration Number 25609), with the active ingredient aminoethoxyvinylglycine hydrochloride (15% guarantee). The principal claim for this product which is used on apple trees is the control of pre-harvest fruit drop, with the secondary claims that it "may also delay fruit maturity, help maintain fruit quality (e.g. firmness) and may reduce the incidence and/or severity of watercore". ReTain Plant Growth Regulator is applied four weeks before the anticipated harvest date and therefore has a different use pattern than SmartFresh Technology.

For protection against storage scald, three products are registered in Canada:

- No Scald DPA EC-283, Registration Number 13471, containing a.i. diphenylamine;
- Shield DPA 15%, Registration Number 18983, containing a.i. diphenylamine; and
- Deccoquin 305, Registration Number 13544, containing a.i. ethoxyquin.

#### **Non-chemical control practices**

Low temperature or controlled atmosphere storage have been used to maintain fruit quality by delaying ripening. Apples can be stored in a refrigerated air facility at low temperatures of 0–3°C, with the storage temperature being cultivar specific, or apples can be stored under controlled atmosphere conditions. Controlled atmosphere storage facilities are airtight and are maintained at low temperatures of usually 0–3°C. They have an altered gaseous composition in which oxygen (O<sub>2</sub>) levels are typically 2.0–3.0% and CO<sub>2</sub> levels are 2.0–3.0% or 4.5–5.0%. Recommendations for temperature, O<sub>2</sub> and CO<sub>2</sub> are specific to cultivar and local conditions. Compared to low temperature air storage, controlled atmosphere storage is more effective in maintaining fruit firmness and acidity for longer storage periods, i.e. greater than 5 to 6 months. Fruit firmness and titratable acid retention may be further improved for some apple cultivars, such as McIntosh, Cortland, Spartan, Golden Delicious and Red Delicious, by storing fruit under low O<sub>2</sub> controlled atmosphere regimens in which O<sub>2</sub> concentrations are reduced from the conventional 2.0–3.0% to 1.0–1.5%.

## **Chemical control practices**

There are no alternative products registered for application to apples in enclosed food storage or distribution facilities to maintain fruit firmness. The only chemical-based practices that are available to maintain fruit quality or reduce the incidence of storage scald are those mentioned above. SmartFresh Technology should not be applied in mixture with any other products.

### **5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management**

The purpose of this product is to control the undesirable side effects (ethylene production) of the natural maturation process that occurs when fruit are stored. SmartFresh Technology is compatible with current management practices for maintaining apple quality while in storage. Storage in refrigerated air or controlled environments are the most widely used methods of keeping apples fresh. SmartFresh Technology is compatible with both types of storage methods. Integrating SmartFresh Technology as a postharvest, pre-storage tool will further limit the maturation process.

### **5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance**

SmartFresh Technology is a plant growth regulator that acts on the hormonal physiology of the fruit. Therefore, development of host resistance to the active ingredient is not an issue.

### **5.5.4 Contribution to Risk Reduction and Sustainability**

Not applicable.

## **6.0 Toxic Substances Management Policy Considerations**

Refer to the Regulatory Note REG2004-07, *1-methylcyclopropene* for an account why 1-MCP does not meet Toxic Substances Management Policy Track-1 criteria.

## **7.0 Summary**

### **Value**

The value data submitted to register SmartFresh Technology are adequate to describe its efficacy for postharvest use on apples to maintain fruit firmness, delay rise in internal ethylene production, delay rise in respiration, delay ripening and senescence, and reduce superficial scald. SmartFresh Technology prolongs the marketing life of apples that enter commercial marketing channels shortly after harvest or following storage in either refrigerated air or under controlled atmosphere conditions.

## **8.0 Proposed Regulatory Decision**

Health Canada's Pest Management Regulatory Agency, under the authority of the *Pest Control Products Act*, is proposing full registration for the sale and use of the technical grade active ingredient 1-methylcyclopropene (1-MCP) Technical and the end-use product SmartFresh Technology on harvested apples to maintain fruit firmness and reduce incidence and severity of superficial scald. An evaluation of current scientific data from the applicant, scientific reports and information from other regulatory agencies has resulted in the determination that, under the proposed conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.



## List of Abbreviations

°C	degree Celsius
1-MCP	1-methylcyclopropene
a.i.	active ingredient
CA	controlled atmosphere
CMP	3-chloro-2-methylpropene
CO <sub>2</sub>	carbon dioxide
EC	emulsifiable concentrate
g	gram
m	metre
m <sup>3</sup>	cubic metre
MRL	maximum residue limit
O <sub>2</sub>	oxygen
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RA	refrigerated air
w/w	by weight



## **Appendix I      Supplemental Maximum Residue Limit Information—International Situation and Trade Implications**

The United States has exempted the tolerance requirements for residues of 1-MCP in/on fruits and vegetables treated via postharvest application for the purpose of controlling/delaying ripening (Federal Register: July 26, 2002).

[www.access.gpo.gov/nara/cfr/waisidx\\_04/40cfr180\\_04.html](http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html):

**Table 1      Comparison of MRLs in Canada and in Other Jurisdictions**

Commodity	Canada (ppm)	United States (ppm)	Codex* (ppm)
Apple	0.01	Exempted	None

\* Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Maximum residue limits (MRLs) may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices.

Under the North American Free Trade Agreement, Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. Harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs specified in this document are necessary. The differences in MRLs outlined above are not expected to impact businesses negatively or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.



## References

### A. List of Studies/Information Submitted by Registrant

#### 5.0 Value

- PMRA 1116725      2005. SmartFresh Concentration Comparisons and Long-Term Commercial Trials of Apples. Final Report.  
DACO: 10.2.3.3,10.2.3.4
- PMRA 1116726      2005. Analysis and Conclusions From Study "SmartFresh Concentration Comparisons and Long Term Commercial Trials of Apples". DACO: 10.2.3.3,10.2.3.4

